time of the inventi n." This rejection as further discussed in Item 4, then relates, how these concerns can be eliminated through depositing the organism identified in the specification as ATCC PTA 2972, together with the further assurances referred to in the Rules. Applicants strongly disagree with this rejection.

While the referred to deposited organism was indeed deposited under the provisions of the Budapest Treaty, the specification and the knowledge in the art at the time of filing of the application, more than adequately describe how a staring organism may be obtained. In the particular case, the Examiner has referred to the organism deposited as ATCC PTA 2972, which is a Sarcocystis neurona organism.

The witten description, in the Background Of The Invention (pgs. 2-3) describes the disease in question, equine protozoal myeloencephalitis ("EPM"), and one of its causative agents; the opossum as its definitive host; and the horse as what is believed to be an aberrant dead-end host. On page 7 of the specification, the pecification relates that the organism may be obtained from fluids or tissues of equine mammalians diagnosed to have EPM, such as from equine cerebral spinal fluid or sections of spinal cord or brain, as well as, feces or intestinal scrapings of opossums or other wildlife present in endemic locales, and also how such species may be maintained, and in which cells and media. On the bottom of page 7 and continuing on page 8, a number of such Sarcocystis neurona isolates, and wher they may be obtained are also referred to, and, it is further noted that a representaive S. neurona isolate is identifiable with PCR. The specification also contains, for example, in Example 1, beginning on page 14, an illustration of the preparation of a vaccine embodiment of the invention. Moreover, applicants have made of record mumerous references as to how to isolate and identify S. neurona, such as by PCR in, e.g., Tanhauser (1999) – item numbered 40 in the IDS.

In view thereof, applicants submit that the starting organism(s) herein concerned, were available and identifiable at the time of filing, and the written description more than adequately fulfills the requirements of the first paragraph of 35 USC 112. Withdrawal of this rejection is therefore respectfully solicited.

Second Rejection Under 35 USC 112 – Item 5 of the Office Action

In this rejection, claims 5-8 and 10-14 have been rejected under 35 USC 112, 1st paragraph, the rejection alleging that the specification "does not reasonably provide enablement for a vaccine;" and while acknowledging that the specification indeed describes vaccine preparation, adjuvant formulation, Ab response to a vaccine, vaccination, IFA serology, and *in vitro* plaque reduction, the rejection argues that the specification fails to show whether or not the antibody was protective against infection. Further, the rejection argues, that while the specification describes the generation of antibody response, it is not clear how this correlates with immunity.

Applicants again strongly disagree.

As the Examiner has acknowledged the specification clearly describes the making and using of a vaccine, but is not sure that there is sufficient (any ?) correlation between the vaccine prepared and the tests provided to show that it is operative in producing the protective immunity for preventing or ameliorating EPM. However, in addition to describing how it is made used, applicants have also provided such correlation. First, in Example 2, the specification demonstrates that in the equines vaccinated with the claimed vaccine, the preparation f which is described in Example 1, the vaccine induced immunogenicity. Secondly, the study and results

described in Example 3, established that the antibody found by IFA in the serum of the horses vaccinated in Example 2 affected a pronounced reducti n in the number of plaques of viable organisms – they were neutralized. The IFA study, in fact was accepted by the USDA as basis of a conditional license, enabling actual commercialization and marketing of the vaccine.

In view thereof, applicants respectfully submit, that the specification does fully enable the vaccine defined in claims 5-8 and 10-14, and the rejection based 35 USC 112, 1st paragraph, should therefore also be withdrawn.

Third Rejection Under 35 USC 112 – Item 6 of the Office Action

In this rejection, various terminology in some of claims 1-2, 4-8 and 10-14 have been rejected under the second paragraph of 35 USC 112 as being indefinite.

The rejection first alleges that the term "capable" in claim 1 is a relative term is an indefinite term, and is, therefore, indefinite. It is submitted that the basis for the rejection is misapprehended, because it ignores the surrounding language in that claim. In that respect "capable" has to be read in association with its continuation, reading, "capable of inducing a merozoite or tachyzoite antibody immune response,", i.e., the same sort of response as demonstrated in the specification, illustratively, in Examples 1-2, that being "merozoite antibody immune response" if from an S. neurona original organism/antigen, and "tachyzoite antibody immune response", if from a Neospra hughesi original organism/antigen..

The term "optionally", in claim 5, has also been deemed a relative term and indefinite. However, the ordinary meaning of optionally is simply, with or without. As such, it is surely not indefinite to those skilled in the art.

With respect to the indefiniteness or lack of clarity directed to "about 1% to 50%" and "about 5% to 20%" in claims 10-11, the rejection is simply not understood. The metes and bounds and those percentages are "wt/wt", and that language is part of the claim.

The metes and bound of the phrase "sufficient quantity" and its alleged indefiniteness, are not indefinite when read with language that follows in those claims, which defines the sufficient quantity in terms of a specified amount of inactivated cells per unit dose, which is measurable.

Similarly, in claims 8-9, the "amount sufficient" has been defined as an amount which is protozocidal, and thus term is also not indefinite to one skilled in the art.

Similarly, the rejections questions what was intended by the phrase "an effective immunizing amount" in claim 5. Again, the phrase seems to have been read in isolation. The phrase defines the vaccine of claim 5 as having that amount of the component of claim 1 which is useful for preventing or ameliorating EPM infection or disease. It could not be clearer to one skilled in the art.

In view thereof, applicants respectfully submit that the phrases and words do meet the requirements of the second paragraph of 35 USC 112, and the rejection respectfully has been traversed and should be withdrawn.

Rejection Under 35 USC 102(b)

Claims 1, 2 and 4 were rejected as anticipated under 35 USC 102(b), as anticipated by Granstrom (1993), the Examiner noting that, in this rejection, the claims are viewed in perspective of the elected species drawn to inactivated S. neurona merozites., and in view of Granstrom allegedly teaching 8 different immunologically active components of S. neurona. The rejection continues that while Granstrom DOES NOT teach that the composition (the claimed or the ones Granstrom disclosed ??) is useful for preventing or ameliorating EPM disease, the intended use does not impart any critical weight on the physical preparation claimed or its patentability.

Applicants respectfully traverse this rejection. Granstrom, in the context of the elected species noted by the Examiner, contains no teaching, explicit or otherwise, that he administered any inactivated S. neurona cells to generate an immunologically active component. Rather, he appears to have either isolated S. neurona antisera from infected horses or from rabbit antisera prepared conventionally using live S. neurona. Therefore, Granstrom cannot possibly anticpate uinder 35 USC 102(b), and the rejection should be withdrawn.

In view of the remarks and hereinabove made it is respectfully submitted that this application and all pending are in condition for further prosecution and allowance.

Reconsideration and an early allowance are therefore earnestly solicited.

Respectfully submitted,

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